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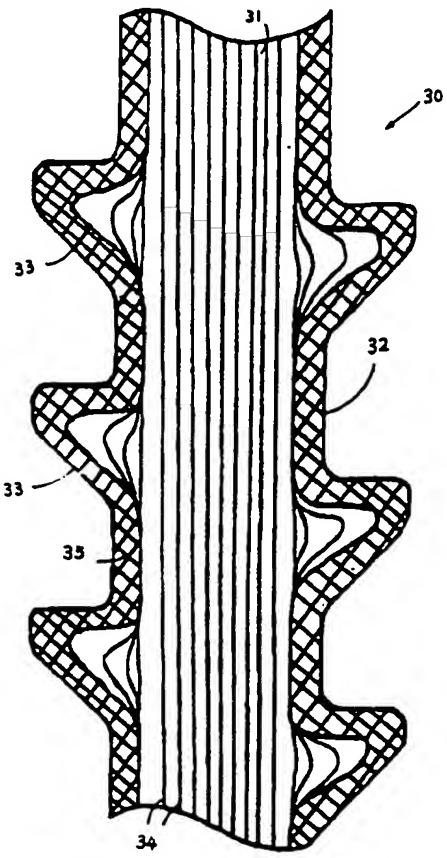
(54) Title: COMPOSITE THREADED COMPONENT AND METHOD OF MANUFACTURE

(57) Abstract

A threaded fastener (30) and its method of manufacturing provides a low modulus osteo-inductive fastener with a high resistance to insertion torquing. The method includes the steps of forming an elongate central core (31), applying a sheath of fibers (33) around the core, some fibers being oriented at an angle to the axis of the core, and then deforming the sheath to form a helical thread.



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COMPOSITE THREADED COMPONENT AND METHOD OF MANUFACTURE

The present invention relates to surgical devices, namely orthopedic fasteners such as threaded rods, screws and the like, and more particularly to fiber reinforced polymer composite fasteners and a method of making said fasteners.

Metal bone screws are routinely used to attach bone plates or to fix fractured bone fragments or tissue to bone. Most commonly used are bone screws made of 316L stainless steel. Stainless steel has an elastic modulus of about thirty (30) million p.s.i. significantly greater than that of cortical bone (about two (2) million p.s.i.). The presence of a hole in cortical bone acts as a stress concentrator and can weaken the bone. For example, Edgerton, et al. (J. Ortho. Res., 8,851-855, 1990) have shown that a hole size equal to twenty (20) percent of the bone diameter can reduce torsional strength by about thirty four percent (34%).

When steel screws are removed from plated femurs or tibias after fracture healing, the bone often fractures at the open hole remaining upon removal of the screw. Although the tendency for bone fracture may be less with the steel screw in the bone (i.e. filling the hole) the mismatch in elastic modulus between the steel screw and bone can still produce a certain level of stress concentration. A low modulus screw could be left in place and not allow stress shielding of the bone from the presence of the bone plate. The plate (even metal) would maintain acceptable axial and torsional motion at the bone fracture for healing, but because the attachment screws are of low modulus, flexion of the screw can occur allowing load to transfer through the healed bone in a near-normal fashion. Thus a second surgery to remove the device and

screws would not be necessary. A bone screw of low modulus poses a smaller stress concentrator in the bone, thus bone integrity would be similar to that of bone without the bone screws present.

To further assure a minimal or nonexistent reduction in bone strength from the presence of the low modulus screw, the screw or other type of anchoring device could be coated or bonded with hydroxyapatite or another effective osteoinductive (osteogenic) material to fully integrate the surrounding bone with the low modulus screw, further reducing any remaining stress concentration effects.

Various patents have been issued which discuss self-reinforced, absorbable materials having reinforcing elements that are wound at least partially around some axis pertaining to the implant. For example, U.S. Patent 4,968,317 describes a resorbable material in which the reinforcing elements are formed by fibrillating a sheet of the reinforcing material by drawing it.

U.S. Patent 4,743,257 describes a resorbable material in which the reinforcing elements are parallel threads of the same chemical composition as the rest of the implant. U.S. Patent 4,743,257 describes an osteosynthesis composite material which is at least partially absorbable in living tissue. This material comprises an absorbable polymer of copolymer matrix which is reinforced with absorbable polymeric reinforcement elements which have the same chemical element percentage composition as the matrix. The reinforcing element is shown as parallel threads of polymer. International patent application 90/12550 describes a self-reinforced absorbable surgical material characterized in that the reinforcing elements are wound at least partially around some axis penetrating the implant. The spiral orientation of the reinforcing elements is

MISSING AT TIME OF PUBLICATION

DE 2947985 A 1, issued to S. Belych, A. Davydov, G. Chromov, A. Moscenskij, I. Movsovic, G. Rojtberg, G. Voskresenskij, G. Persin and V. Moskvitin, entitled "Biodestruktiver Stoff für Verbindungselemente für Knochengewebe" describes at least partially degradable composites which comprise a copolymer of methylmethacrylate and N-vinlpyrrolidone, which has been reinforced with polyamide fibers or with oxycellulose fibers.

U.S. Patent No. 4,243,775, issued to M. Rosensaft and R. Webb, entitled "Synthetic Polyester Surgical Articles" describes surgical products manufactured of copolymer of glycolic acid and trimethylene carbonate.

U.S. Patent No. 4,329,743, issued to H. Alexander, R. Parsons, I Strauchler and A. Weiss, entitled "Bioabsorbable Composite Tissue Scaffold" describes a composite of a bio-absorbable polymer and carbon fibers, which composite is suitable for manufacturing surgical articles.

U.S. Patent No. 4,343,931, issued to Barrows, entitled "Synthetic Absorbable Devices of Poly(esteramides)" describes absorbable polyesteramides, which are suitable for manufacturing of surgical implants.

Patent Application EPO 0,146,398, issued to R. Dunn and R. Casper entitled "Method of Producing Biodegradable Prosthesis and Products therefrom" describes a method for manufacturing of biodegradable prostheses about biodegradable polymer matrix which is reinforced with biodegradable ceramic fibers.

WO 86/00533, issued to J. Leenslag, A. Pennings, R. Veth and H. Jansen entitled "Bone Implant" describes an implant material

for reconstructive surgery of bone tissue, which material comprises a biodegradable porous polymer material and biodegradable or biostable fibers.

The publication of D. Tunc, "A High Strength Absorbable Polymer for Internal Bone Fixation", 9th Annual Meeting of the Society for Biomaterials, Birmingham, Alabama, April 27-May 1, 1983, p. 17, describes a high strength absorbable polylactide, with an initial tensile strength about 50-60 MPa and which material retains a significant part of its initial strength 8-12 weeks after the implantation. This material can be considered suitable to be applied as basic material in manufacturing of internal bone fixation devices which are totally absorbable in living tissues.

The publication of D. Tunc, M. Rohovsky, W. Lehman, A. Strogwater and F. Kummer entitled "Evaluation of Body Absorbable Bone Fixation Devices", 31st Annual ORS, Las Vegas, Nevada, January 21-24, 1985, p. 165, describes high strength, totally absorbable polylactide (initial strength 57,1 MPa), which was used as plates and screws for fixation of canine radial osteotomies.

The publication of D. Tunc, M. Rohovsky, J. Zadwadsky, J. Speiker and E. Strauss entitled "Evaluation of Body Absorbable Screw in Avulsion Type Fractures", the 12th Annual Meeting of the Society for Biomaterials, Minneapolis - St. Paul, Minnesota, USA, May 29 to June 1, 1986, p. 168, describes the application of high strength polylactide screws in fixation of avulsion-type fractures (fixation of canine calcaneus osteotomy).

U.S. Patent No. 4,776,329 issued to R. Treharne entitled "Resorbable Compressing Screw and Method", describes a compression screw comprising a non-absorbable compression parts

and a screw. At least the head of the screw comprises material, which is resorbable in contact with tissue fluids.

Self-reinforced absorbable fixation devices have significantly higher strength values than the non-reinforced absorbable fixation devices. U.S. Patent No. 4,743,257 issued to P. Törmälä, P. Rokkanen, J. Laiho, M. Tamminmäki and S. Vainionpää entitled "Material for Osteosynthesis Devices", describes a self-reinforced surgical composite material, which comprises an absorbable polymer or copolymer, which has been reinforced with absorbable reinforcing elements, which have the same chemical element composition as the matrix.

FI Patent Application No. 87 0111, issued to P. Törmälä, P. Rokkanen, S. Vainionpää, J. Laiho, V.-P. Heponen and T. Pohjonen entitled "Surgical Materials and Devices", describes self-reinforced surgical bone fracture fixation devices which have been manufactured at least partially of fibrillated absorbable material(s).

According to the publication of T. Pohjonen, P. Törmälä, J. Mikkola, J. Laiho, P. Helevirta, H. Lähde, S. Vainionpää and P. Rokkanen entitled "Studies on Mechanical Properties of Totally Biodegradable Polymeric Rods for Fixation of Bone Fractures", VIth International Conference PIMS, Leeuwenhorst Congress Center, Holland, 12-14 April 1989, p. 34/1-34/6, self-reinforced absorbable surgical materials have excellent strength properties, e.g. SR-polyglycolide had bending strength 415 MPa and SR-polylactide 300 Mpa.

In the publication of D. Tunc and J. Jadhav entitled "Development of Absorbable Ultra High Strength Polylactide", Am. Chem, Soc., 196th ACS Meeting, Abstracts of Papers, L.A.,

California, Sept. 25-30, 1988, p. 383-387, a good tensile strength (300 MPa) for fibrillated SR-polylactide was measured.

The publication of E. Partio, O. Böstman, S. Vainionpää, H. Pätiälä, E. Hirvensalo, K. Vihtonen, P. Törmälä and P. Rokkanen entitled "The Treatment of Cancellous Bone Fractures with Biodegradable Screws", Acta Orthop. Scand., 59(5), 1988, p. 18, describes the fixation of cancellous bone fractures with self-reinforced absorbable screws, which have a flat head, which head can be located to a slot at the tip of the screwdriver in order to drive the screw into a channel made into the bone.

The following patents relate to absorbable (biodegradable or resorbable) polymers, copolymers, polymer mixtures, or composites: U.S. Patent No. 3,297,033; U.S. Patent No. 3,636,956, U.S. Patent No. 4,052,988; U.S. Patent No. 4,343,931; U.S. Patent No. 3,969,152; U.S. Patent No. 4,243,775; FI Patent Appln. No. 85 5079, FI Pat. Appln. No. 86 0366; FI Patent Appln. No. 86 0440 and FI Pat. Appln. No. 88 5164.

However, bioabsorbable screws still may give problems in that their strength degrades after insertion as they are gradually absorbed and that they may leave a hole in the bone when they have degraded which may take time to fill with normal bone. There is thus a need for a bone screw which need not be removed and which has a modulus similar to that of bone. One such bone screw is described in WO 94/07425. That bone screw includes a plurality of fibres in a polymer matrix and the fibres are pre-torqued to provide the bone screw with a high resistance to insertion torquing so that the screw is less likely to break on or after insertion into the bone.

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It is an object of the present invention to provide an alternative composite orthopaedic threaded device, and a method for its manufacture, which has improved mechanical properties compared with prior composite threaded devices.

According to the invention a threaded orthopaedic device formed of a fibre-reinforced polymeric material comprises an elongate shank, having a central core and a helical thread characterised in that said helical thread comprises a sheath of fibres of which at least some are oriented at an angle to the longitudinal axis of the shank.

A method, according to the invention, for forming a threaded orthopaedic device of a fibre-reinforced polymeric material comprises:

(a) forming an elongate core of a fibre-reinforced polymeric material

(b) placing a sheath around the core, said sheath comprising fibres which are oriented at an angle to the longitudinal axis of the core

(c) forming a helical thread around said core by deforming the core and sheath construction to the desired shape.

Because of the low modulus and minimal stress concentration effects, a bone screw of the present invention is designed to remain in the bone without the need for a second surgery. Even if a metal bone plate is used, the lower modulus neck region of the present screw will flex to some degree and not allow stress shielding at the healed bone fracture to occur as is the case with current metal screws. Thus even a metal bone plate attached by the present composite bone screw may be left in place, thereby avoiding a second surgery.

The core may be formed by any method but methods which achieve the preferred longitudinal orientation of the fibres are preferred. The most preferred method is pultrusion. The sheath of fibres which comprise the helical thread may be applied as narrow strips of unidirectional prepreg or as individual fibres or tows of fibres. Where fibres or tows are used an additional quantity of polymer should be supplied to bind the fibres into a composite to form the helical thread. This polymer may be in the form of a powder, which may be already present in a commercially sourced tow of fibres, or it may be added during the manufacturing process. Alternatively molten polymer may be applied to the prepared core and sheath of fibres by dipping or spraying for example. The polymer may advantageously but not necessarily be similar to that used in the core and is preferably self-curable, heat curable or thermoplastic.

The polymeric material forming the core and/or the helical thread is preferably either a polyether ether ketone (PEEK) or a polyether ketone ether ketone ketone (PEKEKK). When the device is intended for implantation e.g. a bone screw, the materials used are very preferably biocompatible. Suitable fibres are formed of carbon or aramid.

Other parts of the device, e.g. a head portion, may be formed in the same process as the thread or may be formed separately. A head portion may advantageously include circumferentially wound fibres for added strength and to provide resistance to torque during insertion by the screw driver or like driving implement.

The invention will now be further described, by way of example only and with reference to the accompanying drawings, which are:

FIGURE 1, a longitudinal sectional view of a part of a threaded fastener according to the invention made in accordance with the method of the present invention.

FIGURE 2 is a schematic view illustrating test results of the torquing of a simulated bone with an opening in the simulated bone;

FIGURE 3 is a schematic view illustrating test results of the torquing of a simulated bone, and with a metallic bone screw occupying an opening in the bone;

FIGURE 4 is a schematic view illustrating test results of the torquing of a simulated bone, and with a bone screw occupying an opening in the bone wherein the bone screw has a modulus that is similar to that of the bone; and

In Figure 1, a threaded fastener is shown that has been manufactured using the method of the present invention. Threaded composite fastener 30 is formed by initially forming a unidirectional core 31, i.e. a core in which the fibres (34) are oriented in the direction of the longitudinal axis. The core 31 is preferably pultruded and has a diameter slightly less than the inside diameter (minor diameter, root diameter) of the thread to be produced. The unidirectional core 31 provides a high tensile (and flexural) strength and stiffness along the axis of the component and serves as a mandrel for the subsequent braiding operation.

In the second method step, a sheath 32 is braided or wound over the core using narrow strips of unidirectional prepreg or individual fibers or individual tows (35) oriented at various angles (typically 0 degrees and plus or minus 45 degrees) to the axis of the component.

The sheath 32 can be consolidated as it is braided or wound. The sheath 32 provides a high degree of strength to the threads 33. The last step of the process is a threading operation. Threads are produced by either hot rolling or cold rolling, depending on the matrix material selected. High glass transition temperature (Tg) (with respect to ambient) matrix materials preferably require hot rolling while low Tg materials may be cold rolled. If carbon fibers are utilized as reinforcement, heating of the composite material may be accomplished by placing an induction coil around the mandrel or core 31 just ahead of the rollers. Alternatively, hot air jets or heat lamps may be employed for heating the material. Rolling provides a means for producing threads without causing significant damage to the fibers or exposing the fibers to the environment as is the case with machining operations.

The method and fastener of Figure 1 can be applied to the production of prototype threaded composite rods for use with Ilizarov type fastener systems, such as those shown and described in the Jamison et al. Patent No. 5,062,844, entitled "Method And Apparatus For The Fixation Of Bone Fractures, Limb Lengthening And The Correction Of Deformities", hereby incorporated herein by referenced. The primary advantages of composite rods over the steel rods currently used are significantly reduced weight, radiolucency, and compatibility with magnetic resonance imaging (MRI) equipment. Potential secondary advantages include increased strength and increased stiffness. This technique may be applied to produce other threaded components of Ilizarov type fixation systems including half-pins as well as other trauma products such as bone screws.

As an example, threaded fasteners 30 can consist of a 0.125" diameter pultruded core 31 consisting of unidirectional AS4 carbon fibers (Vf - 0.60) in a polyetheretherketone (PEEK) matrix. A 0.056" thick sheath 32 is braided over the core 31 using 0.080" wide strips of unidirectional AS4/PEEK prepreg. The braid pattern incorporates 0° (27%) and ± 45° (73%) fiber orientations. Standard (e.g., M-6 (6mm diameter - 1mm pitch)) threads are rolled onto the rods using commercially available rolling equipment such as manufactured by Teledyne Landis.

Figures 2, 3 and 4 are photographs that demonstrate the results of a torsion test that demonstrates the effect of holes and filled holes on stress concentration. To demonstrate the effect of holes and filled holes on stress concentration, 6 mm diameter holes were drilled in 18 mm diameter wood cylinders (15 cm long) with a wall thickness of 2.5 mm. In one case the hole was left unfilled (Figure 2). In another case, a hard stainless steel dowel was press-fit into the hole (Figure 3). In the final case, a low modulus (wood) dowel was press-fit and glued (epoxy) into the hole to simulate a bioactive material (hydroxyapatite) coated-low modulus screw (Figure 4). The samples were loaded in torsion in a Bionix MTS machine and compared to tests in which no hole was present. The wood cylinders were filled with a wood insert (1.5 cm long) for gripping at each end. Results are given below in Table 1, and show the dramatic reduction (48%) in strength due to the hole. Importantly, this reduction in strength is still present with a pressed steel dowel (i.e., bone screw), while the glued, low modulus, wood dowel completely restores the strength.

Figures 2, 3, and 4 show clearly how the crack initiates at the hole whether unfilled (Figure 2) or filled with the tight stainless steel dowel pin (Figure 3). However, when the pin is an integral part of

the wood cylinder, the hole effect can be eliminated and the crack due to torsional loading can initiate anywhere along the cylinder. Notice in Figure 4 that the crack did not initiate from the hole region.

TABLE 1. RESULTS OF THE TORSION TESTS

Condition	Average Peak Torque (Nm)	Torsional Energy (Area Under Torque -Rotation Curve) Nm-Deg.	Reduction in Strength
No hole	10.3	75.7	———
Hole (unfilled)	7.8	39.3	48%
Hole with steel dowel	7.0	33.2	56%
Hole with glued wood dowel	10.7	75.4	<1%

Perhaps even more important is that a permanent, low-modulus screw with an osteoinductive coating would not have to be removed.

CLAIMS

1. A threaded orthopaedic device formed of a fibre-reinforced polymeric material comprises an elongate shank having a central core (31) and a helical thread (33) characterised in that said helical thread comprises a sheath of fibres (35) of which at least some are oriented at an angle to the longitudinal axis of the shank.

2. An orthopaedic device as claimed in claim 1, wherein substantially all of the fibres of the core are oriented in a direction substantially parallel to the longitudinal axis of the shank.

3. The threaded device of either claim 1 or 2 wherein the polymeric material is a polyetheretherketone (PEEK) material.

4. The threaded fastener of either claim 1 or claim 2 wherein the polymeric material is a polyetherketoneethereketoneketone (PEKEKK) material.

5. The device of any of claims 1 - 4 wherein the fibers are carbo-fibers.

6. The device of any of claims 1 - 4 wherein the fibers are aramid fibers.

7. The device of any of claims 1 - 6 wherein some of the fibers which form the helical thread are oriented at an angle of about forty-five degrees (45°) relative to the central longitudinal axis of the shank portion.

8. The device of any of claims 1 - 7 comprising a fiber sheath that is braided over the core.

9. The device of claim 8 wherein the braid includes a braid pattern that incorporates at least 0 degree and 45 degree fiber orientations.

10. The device of claim 8 wherein the braid includes a winding pattern that incorporates at least 0 degree and 45 degree fiber orientations.

11. The device of any of claims 1 - 7 comprising a fiber sheath that is wound over the core.

12. The device of any of claims 1 - 7 wherein the sheath comprises strips of unidirectional prepreg.

13. The device of any of claims 1 - 11 wherein the sheath comprises tows of fibers.

14. The device of any of claims 1 -11 wherein the sheath comprises individual fibers.

15. The threaded device of any of claims 1 - 14 wherein the device is a threaded rod.

16. The device of any of claims 1 - 14 which is a bone screw.

17. The device of any of claims 1 - 14 which is a bone bolt.

18. The device of any of claims 1 - 17, further comprising a coating of an osteoinductive material.

19. A method for forming a threaded orthopaedic device of a fibre-reinforced polymeric material comprises the steps of

(a) forming an elongate core of a fibre-reinforced polymeric material;

(b) placing a sheath around the core, said sheath comprising fibres which are oriented at an angle to the longitudinal axis of the core; and

(c) forming a helical thread around said core by deforming the core and sheath construction to the desired shape.

20. The method of claim 19, wherein a large proportion of the fibres of the core are oriented in a direction parallel to the longitudinal axis of the core.

21. The method of claim 20 wherein said elongate core is formed by pultrusion.

22. The method of any of claims 19 - 21 wherein the threads are formed by rolling.

23. The method of claim 22 wherein the threads are formed by hot rolling.

24. The method of claim 22 wherein the threads are formed by cold rolling.

25. The method of any of claims 19 - 24 wherein said sheath comprises braided fibres.

26. The method of any of claims 19 - 24 wherein said sheath comprises fibres wound around said core.

27. The method of any of claims 19 - 24 wherein said sheath comprises strips of unidirectional prepreg.

28 The method of any of claims 19 - 27 wherein said sheath comprises tows of fibres.

29. The method of any of claims 19 - 28 wherein a polymeric material is added to the fibres of said sheath before step (c).

30. The method of claim 19 wherein the polymer is a self-curing polymer.

31. The method of claim 19 wherein the polymer is a heat curing polymer.

32. The method of claim 19 the polymer is a thermoplastic powder.

33. A threaded orthopaedic fastener formed according to the method of any of claims 19 - 32.

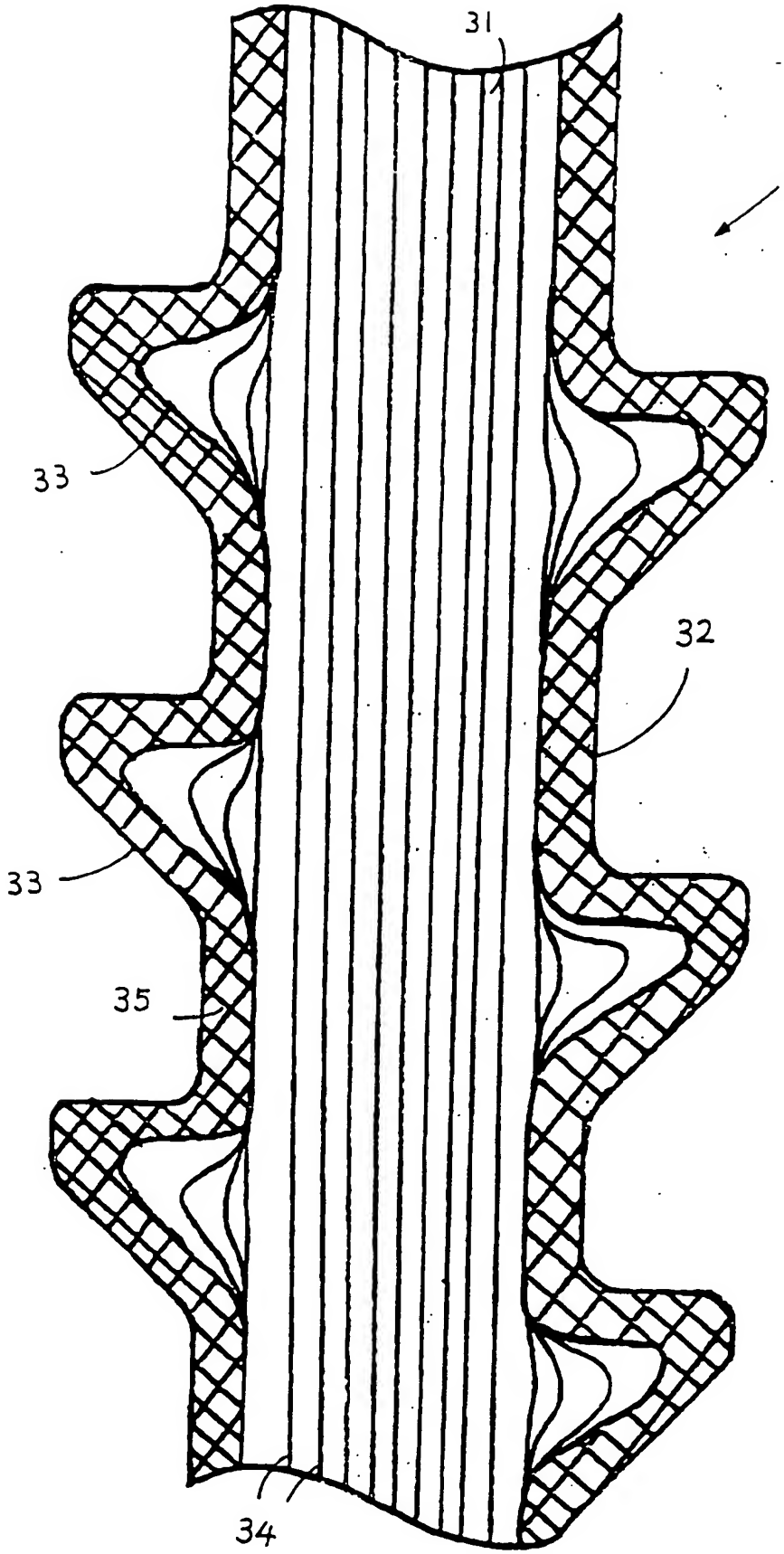

FIG. 1

FIG. 2

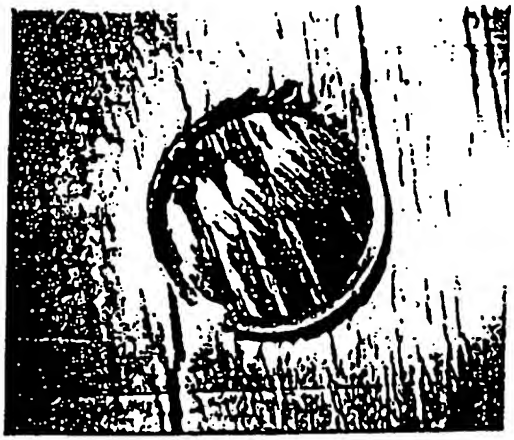

FIG. 3

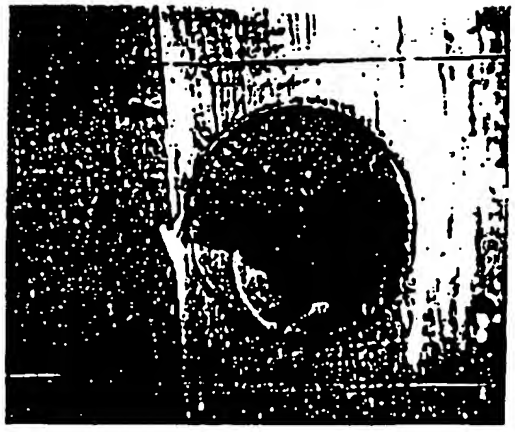

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/11847

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61B 19/00
US CL :606/73; 623/16
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/65, 73, 76; 623/11, 16, 18, 66

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,743,257 (TORMALA ET AL.) 10 May 1988, see entire document.	1-33
Y, P	US, A, 5,397,365 (TRENTACOSTA) 14 March 1995, see columns 1 and 2.	1-33
A	US, A, 5,181,930 (DUMBLETON ET AL.) 26 January 1993, see Abstract.	1-33
A	US, A, 4,902,297 (DEVANATHAN) 20 February 1990, see entire document.	1-33
A	US, A, 4,192,021 (DEIBIG ET AL.) 11 March 1980, see entire document.	1-33

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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